Health Decisions, Inc.

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Notice of Independent Review Decision

August 17, 2015

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE: Anterior Lumbar Interbody Fusion L5-S1, Posterior Lumbar Fusion L5-S1, Inpatient Stay for 3 days, and Trimod Back Brace.

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION: American Board Certified Orthopedic Surgeon with over 13 years' experience.

REVIEW OUTCOME:

Upon independent review, the reviewer finds that the previous adverse determination/adverse determinations should be:

☒ Upheld (Agree)

Provide a description of the review outcome that clearly states whether medical necessity exists for each of the health care services in dispute.

PATIENT CLINICAL HISTORY [SUMMARY]:
This is a male who injured his back on xx/xx/xx after lifting heavy objects. He was diagnosed with lumbar spine degenerative disk disease. The request is for Anterior Lumbar Interbody Fusion, Posterior Lumbar Fusion, Inpatient for 3 days, and Trimod Back Brace. He was treated with medications, physical therapy with did not provide improvement. He has also had 2 ESI one on 5/13/13 which provided some relief and one on 07/19/13 which did not provide relief. Lumbar spine MRI dated 03/10/14 showed L5-S1 DDD. Lumbar Spine CT discogram dated 05/08/15 showed L5-S1 annual tear and grade 1 anterolisthesis. The more recent records indicate that the patient still complains of low back pain and leg pain.

05/11/15: Office notes: Pt is here for follow up in regards to his back and leg pain. Rates pain 8/10 with 60% back pain 40% right leg pain. His back is in the right paracentral and right paraspinous regions at the L5-S1 level radiating to the right buttock and right posterior thigh and calf. Additionally he has right lateral thigh and groin pain. Pt did have the discogram performed on 05/08/15. Review of symptoms: Denies headaches, dizziness, SOB, chest pain, ABD pain, or bowel or bladder changes. Pt is alert and oriented. Affect is appropriate. BP 150/90 HR 67. The pt does continue to walk with an antalgic gait favoring the right lower extremity. Lumbar Spine exam: The pt does have tenderness to palpation in the midline and right paracentral regions at the L5-S1 level as well as pain over the right sciatic notch. He has 20 degrees of forward flexion and 5-10 degrees of back extension both with pain where flexion is more painful than extension. Neuro exam: Positive straight leg test and Lasegue's testing on the right negative on the left. Sensory is intact in the lower extremities. Pt has negative ankle clonus and negative Babinski sign bilaterally. Musculoskeletal Exam: There is 4+/5 weakness over the right gastroc soleus and EHL compared to 5/5 on the right. There is 5/5 hip flexion, leg extension, leg flexion, and tibialis anterior testing bilaterally. Outside Testing Results:

Results of the discogram were reviewed from 05/08/15 showing normal disc height and morphology at L4-L5 with no pain during the procedure. Morphology at the L5-S1 level showed circumferential tearing with bulge causing concorinate low back and right leg pain rated just 7/10. We are unable to open the disc for the CT results. Impression: 1. Lumbar sprain/strain 2. Lumbar disc displacement, 3. L5-S1 3 Lumbar radiculopathy. Plan: At this point the patient has failed conservative therapy, being physical therapy and not epidural steroid injections. He has had a psychiatric evaluation showing that he is a good candidate for lumbar fusion, as well as a CT discogram. We were unable to view the CT scan; therefore we will request a copy from Crown Imaging. Upon review of the CT scan, disc, and results, we will most likelysubmit for lumbar fusion. He has measured for a brace today being 42".

06/08/15: Office notes: Pt reports pain today 8/10 with 50% right paraspinous low back pain radiating to the right later leg and he also complains of burning pain in the planar aspect of the right foot. He did have physical therapy in 2013 where he had more than 10 sessions without relief. He also had an epidural steroid injection in 2013 where he had one week of significant relief. Pt still favoring the right lower extremity with an antalgic gait. Pt has tenderness to palpation in the right lower lumbar spine. He has 20 degrees of forward flexion and 5-10 degrees of back extension both with pain where flexion is more painful than extension. Positive straight leg test and Lasegue's testing on the right negative on the left. Sensory to light touch is decreased in the right lateral thigh, calf and foot otherwise intact. Pt has negative ankle clonus and negative Babinski sign bilaterally. No change in musculoskeletal exam. Plan: CT results reviewed. CT shown to be positive and concordant at L5, S1, which correlates with his symptoms. I have recommended that he move forward with anterior interbody fusion at Le-S1 along with posterior transpedicular decompression at L5-S1 on the right and subsequent application of posterior instrumentation and fusion. His claim has been delayed extensively by xxxxx due to the extent of injury disputes.

06/19/15: UR: Based on the clinical information submitted for this review and using the evidenced- based, peer-reviewed guidelines this request is non-certified. Although the patient remains symptomatic despite prior non-operative, it is unclear if the L5-S1 level is the current pain generator as the records did not include the discogram report with a control level noting concordant pain at L5-S1 with a negative control level.

07/31/15: Office notes: Pt is still in pain today 8/10. His request for reconsideration of lumbar fusion was once again denied by insurance. At this point he has failed conservative therapy in the form of physical therapy and epidural steroid injections. The court has included disc bulging, disc disruption, annular tear and foraminal narrowing at L5-S1 to be part of his compensable injury. His extent of injury issues have been adjudicated, to include diagnosis that include the L5-S1 disc. Therefore, xxxxx would recommend the request for fusion surgery to be sent to IRO.

07/22/15: UR: This in a non-certification of an appeal request for Anterior Lumbar Interbody Fusion, Posterior Lumbar Fusion, Inpatient for 3 days, and Trimod Back Brace. The previous non-certification of June 19, 2015, was due to lack of discography report. Additional medical records were provided for review for the appeal process in the form of discography operative report. The previous non-certification is supported. The discography report indicated that there was abnormal morphology of the L5-S1 disc with concordant pain reproduced upon pressurization; however as noted in the ODG, discography may be supported if the decision has already been made to do a spinal fusion and negative discogram could rule out the need for fusion on the disc, but a positive discogram in itself would not justify fusion. The guidelines state that fusion is indication for treatment of neural arch defects, instability, and revision after previous failed operations, as well as cases of infection, tumor, or deformity. There was no documentation of infection, tumor deformity or previous surgery at the L5-S1 level; however there was noted to be a grade 1 only. Flexion and Extension radiographs documented no instability. Based on this, the need for fusion of the L5-S1 segment over less invasive surgical management was not substantiated, and as such, the requested surgical procedure is not supported, the request for a three day inpatient stay is not supported. A standard off the shelf brace is supported over the use of a custom post op brace after fusions. The appeal requested for Anterior Lumbar Interbody Fusion, Posterior Lumbar Fusion, Inpatient for 3 days, and Trimod Back Brace is not certified.

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS, AND CONCLUSIONS USED TO SUPPORT THE DECISION:

The request for anterior lumbar interbody fusion L5-S1, posterior lumbar fusion L5-S1, inpatient stay for 3 days, and Trimod Back Brace is denied.

The patient is currently complaining of pain in the back and right leg. His MRI demonstrates degenerative disc disease at L5-S1 with a grade I spondylolisthesis.

The Official Disability Guidelines (ODG) supports lumbar spine fusion in patients with the following diagnoses: instability, multiple failed decompressions, spinal cord injury, spinal infections, spinal deformity, and tumor. The ODG requires documentation of segmental instability for patients with spondylolisthesis.

The medical record does not document any evidence of instability on flexion and extension views of the lumbar spine.

Furthermore, there is no advantage of the Trimod Back Brace over a standard LSO.

The requested surgery is not medically necessary based on the ODG criteria.

PER ODG:

Patient Selection Criteria for Lumbar Spinal Fusion:

(A) *Recommended* as an option for the following conditions with ongoing symptoms, corroborating physical findings and imaging, and after failure of non-operative treatment (unless contraindicated e.g. acute traumatic unstable fracture, dislocation, spinal cord injury) subject to criteria below:

(1) Spondylolisthesis (isthmic or degenerative) with at least one of these:
  (a) instability, and/or
  (b) symptomatic radiculopathy, and/or
  (c) symptomatic spinal stenosis;
(2) Disc herniation with symptomatic radiculopathy undergoing a third decompression at the same level;
(3) Revision of pseudoarthrosis (single revision attempt);
(4) Unstable fracture;
(5) Dislocation;
(6) Acute spinal cord injury (SCI) with post-traumatic instability;
(7) Spinal infections with resultant instability;
(8) Scoliosis with progressive pain, cardiopulmonary or neurologic symptoms, and structural deformity;
(9) Scheuermann's kyphosis;
(10) Tumors.

(B) *Not recommended* in workers' compensation patients for the following conditions:

(1) Degenerative disc disease (DDD);
(2) Disc herniation;
(3) Spinal stenosis without degenerative spondylolisthesis or instability;
(4) Nonspecific low back pain.

(C) *Instability criteria:* Segmental Instability (objectively demonstrable) - Excessive motion, as in isthmic or degenerative spondylolisthesis, surgically induced segmental instability and mechanical intervertebral collapse of the motion segment and advanced degenerative changes after surgical discectomy, with relative angular motion greater than 15 degrees L1-2 through L3-4, 20 degrees L4-5, 25 degrees L5-S1. Spinal instability criteria includes lumbar inter-segmental translational movement of more than 4.5 mm. (Andersson, 2000) (Luers, 2007) (Rondinelli, 2008)

(D) After failure of two discectomies on the same disc [*(A)(2) above*], fusion may be an option at the time of the third discectomy, which should also meet the ODG criteria. (See ODG Indications for Surgery -- Discectomy.)

(E) Revision Surgery for failed previous fusion at the same disc level [*(A)(3) above*] if there are ongoing symptoms and functional limitations that have not responded to non-operative care; there is imaging confirmation of pseudoarthrosis and/or hardware breakage/malposition; and significant functional gains are reasonably expected. Revision surgery for purposes of pain relief must be approached with extreme caution due to the less than 50% success rate reported in medical literature. Workers compensation and opioid use may be associated with failure to achieve minimum clinically important difference after revision for pseudoarthrosis (Djurasovic, 2011) There is low probability of significant clinical improvement from a second revision at the same fusion level(s), and therefore multiple revision surgeries at the same level(s) are not supported.

(F) *Pre-operative clinical surgical indications* for spinal fusion should include all of the following:

(1) All physical medicine and manual therapy interventions are completed with documentation of reasonable patient participation with rehabilitation efforts including skilled therapy visits, and performance of home exercise program during and after formal therapy. Physical medicine and manual therapy interventions should include cognitive behavioral advice (e.g. ordinary activities are not harmful to the back, patients should remain active, etc.);

(2) X-rays demonstrating spinal instability and/or myelogram, CT-myelogram, or MRI demonstrating nerve root impingement correlated with symptoms and exam findings;

(3) Spine fusion to be performed at one or two levels;

(4) Psychosocial screen with confounding issues addressed; the evaluating mental health professional should document the presence and/or absence of identified psychological barriers that are known to preclude post-operative recovery;

(5) For any potential fusion surgery, it is recommended that the injured worker refrain from smoking for at least six weeks prior to surgery and during the period of fusion healing; (Colorado, 2001) (BlueCross BlueShield, 2002)

(6) There should be documentation that the surgeon has discussed potential alternatives, benefits and risks of fusion with the patient;

(7) For average hospital LOS after criteria are met, see Hospital length of stay (LOS).

A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:

- ☐ **ACOEM- AMERICAN COLLEGE OF OCCUPATIONAL & ENVIRONMENTAL MEDICINE UM KNOWLEDGEBASE**
- ☐ **AHCPR- AGENCY FOR HEALTHCARE RESEARCH & QUALITY GUIDELINES**
- ☐ **DWC- DIVISION OF WORKERS COMPENSATION POLICIES OR GUIDELINES**
- ☐ **EUROPEAN GUIDELINES FOR MANAGEMENT OF CHRONIC LOW BACK PAIN**
- ☐ **INTERQUAL CRITERIA**
- ☒ **MEDICAL JUDGEMENT, CLINICAL EXPERIENCE, AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS**
- ☐ **MERCY CENTER CONSENSUS CONFERENCE GUIDELINES**
- ☐ **MILLIMAN CARE GUIDELINES**
- ☒ **ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES**
- ☐ **PRESSLEY REED, THE MEDICAL DISABILITY ADVISOR**
- ☐ **TEXAS GUIDELINES FOR CHIROPRACTIC QUALITY ASSURANCE & PRACTICE PARAMETERS**
- ☐ **TEXAS TACADA GUIDELINES**
- ☐ **TMF SCREENING CRITERIA MANUAL**
- ☐ **PEER REVIEWED NATIONALLY ACCEPTED MEDICAL LITERATURE (PROVIDE A DESCRIPTION)**
- ☐ **OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)**